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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,303	01/14/2004	Yi-You Huang	DF-03500	5393

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EXAMINER	
YANG, NELSON C	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,303	HUANG ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/14/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *15-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-14, drawn to an optical detection method, classified in class 435, subclass 7.1.

   II. Claims 15-22, drawn to an optical detection system for a protein microarray, classified in class 435, subclass 283.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used for filtering and purifying samples.

4. During a telephone conversation with Jonathan Owens on November 7, 2005 a provisional election was made with traverse to prosecute the invention of group I, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-22 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 6-10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lizardi et al [US 6,143,495].

With respect to claim 1, Lizardi et al teach a method for amplifying nucleic acid sequences based on the presence of a specific target sequence or analyte with high specificity and sensitivity (column 2, lines 64-67). By coupling a nucleic acid tag such as open circle probes (OCP) to a specific binding molecule, such as an antibody, rolling circle amplification of the nucleic acid tag can be used to detect analytes in a sample (column 3, lines 17-26). Rolling circle amplification is accomplished by a rolling circle replication primer that is complementary to the primer complement portion of the OCP (column 13, lines 23-30). To aid in detection and quantitation of nucleic acids amplified using RCA and RCT, detection labels can be directly incorporated into amplified nucleic acids or can be coupled to detection molecules (column 13, lines 57-61). Detection labels include radioactive isotopes, fluorescent molecules,

phosphorescent molecules, enzymes, antibodies, and ligands (column 14, lines 1-5), all which could be considered to be nanoparticles.

8. With respect to claims 2-3, Lizardi et al teach specific binding molecules such as an antibody (column 3, lines 17-26), which would bind to antigens.

9. With respect to claim 4, the rolling circle replication primer contains a complementary portion between 10 to 35 nucleotides long and can also contain a non-complementary portion that is 1-100 nucleotides long (column 13, lines 30-55).

10. With respect to claim 6, Lizardi et al teach open circle probes comprising target probe portions, primer complement complement portions, spacer region, detection tag portions secondary target sequence portions, address tag portions, and promotion portions (column 8, lines 38-50), as well as amplification target circles containing between 40 to 1000 nucleotides comprising primer complement portions, detection tag portions, secondary target sequence portions, address tag portions, and promoter portions (column 12, lines 45-55). Lizardi et al also teach the use of DNA polymerase (column 21, lines 8-11), nucleotides (column 222, lines 10-40), and buffers (column 60, lines 20-30).

11. With respect to claims 7, 9, Lizardi et al teach open circle probes comprising primer complement complement portions (column 8, lines 38-50), as well as amplification target circles containing between 40 to 1000 nucleotides comprising primer complement portions (column 12, lines 45-55).

12. With respect to claim 8, Lizardi et al teach that in RCA, a rolling circle replication primer hybridizes to circular OCP or ATC molecules followed by rolling circle replication of the OCP or ATC molecules using a strand-displacing DNA polymerase, wherein rolling circle replication

results in large DNA molecules containing tandem repeats of the OCP or ATC sequence (column 30, lines 25-51).

13. With respect to claim 10, Lizardi et al teach that to aid in detection and quantitation of nucleic acids amplified using RCA and RCT, detection labels can be directly incorporated into amplified nucleic acids or can be coupled to detection molecules (column 13, lines 57-61). Detection labels include radioactive isotopes, fluorescent molecules, phosphorescent molecules, enzymes, antibodies, and ligands (column 14, lines 1-5), all which could be considered to be nanoparticles.

14. With respect to claim 12, Lizardi et al teach that the length of the oligonucleotides in the detection probes can be 10 to 35 nucleotides long (column 15, lines 12-30).

15. Claims 1-3, 5, 7, 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Labaer et al [US 6,800,453].

With respect to claim 1, Labaer et al teach a method in which an antibody can be covalently bound to a derivatized substrate, e.g., using a crosslinker, e.g., N-hydroxy-siccinimidyl ester. The test polypeptides with epitopes such as Flag, HA, or myc are then bound to antibody-coated plates (column 57, lines 55-66). Nucleic acids disposed on the array can be amplified directly on the array by using pimers (column 72, lines 48-65) and using rolling circle amplification (RCA) (column 18, lines 46-57). Labaer et al further teach that the nucleic acid tags can be coupled to insoluble substrates such as nanoparticles (column 59, lines 22-41).

16. With respect to claims 2-3, Labaer et al teach specific classes of binding pairs such as peptide epitopes and monoclonal antibodies, where one member of the binding pair is attached to the substrate (column 57, lines 43-56).

17. With respect to claim 5, Labaer et al teach a nucleic acid that includes a test amino acid sequence and an affinity tag to which a binding agent recognizes (column 2, lines 11-20), where the affinity tag can be a free cysteine (column 58, lines 45-50).

18. With respect to claim 7, each address of the plurality is provided with a nucleic acid, e.g., by pipetting, spotting, printing (e.g., with pins), piezoelectric delivery, or, e.g., other means of mechanical delivery. In a preferred embodiment, the provided nucleic acid is a template nucleic acid, and the method further includes amplifying the template, such as by rolling circle amplification (column 18, lines 46-57).

19. With respect to claims 10-11, Labaer et al further teach that the nucleic acid tags can be coupled to insoluble substrates such as nanoparticles (column 59, lines 22-41) and comprise materials such as gold (column 54, lines 30-31).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lizardi et al. [US 6,143,495], in view of Strathmann [US 6,480,791].

Lizardi et al disclose the invention substantially as claimed, as discussed above. Lizardi fails to teach the use of a quantum dot, using a fluorescence label rather than a quantum dot (column 14, lines 1-5).

Strathmann, however, does teach the use of quantum dots for labeling and further discloses that reaction products may be amplified (col. 31, lines 55-65) and that polynucleotides may be visualized in several different ways including use of fluorescent and quantum dot labels (col. 35, lines 3-13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the fluorescent labels in the Lizardi et al. invention with quantum dots because Strathmann teaches that fluorescent labels and quantum dots are functional equivalents as nucleic acid labels.

22. Claims 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lizardi et al [US 6,143,495] in view of Mirkin et al [US 6,361,944], and further in view of Natan et al, [6,579,726].

Lizardi et al disclose the invention substantially as claimed, as discussed above. Lizardi et al fail to teach the use of spherical nanogold particles.

Mirkin et al however teach that oligonucleotides functionalized with alkanethiols at their 5'-termini readily attach to gold nanoparticles (column 17, lines 15-20) and is well characterized (column 17, lines 8-14). Natan et al further teach that DNA can be detected utilizing metal nanoparticles that are preferably spherical (column 13, lines 31-43) and further teaches that the use of such nanoparticles leads to an 100,000 fold increase in sensitivity using detection means such as SPR (column 3, lines 40-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the 5' end of the oligonucleotides with an –SH group as taught by Mirkin et al in the invention of Lizardi et al, as Mirkin et al. teach that such a modification

provides the advantage of strongly attaching the oligonucleotides to the gold nanoparticles. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to utilize spherical gold nanoparticles, as taught by Natan et al, in the method of Lizardi et al in order to achieve a 100,000 fold increase in sensitivity using detection means such as SPR.

23. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Labaer et al [US 6,800,453], in view of Strathmann [US 6,480,791].

Labaer et al disclose the invention substantially as claimed, as discussed above. Labaer et al fail to teach the use of quantum dots as nucleic acid labels.

Strathmann, however, does disclose that reaction products may be amplified (col. 31, lines 55-65) and that polynucleotides may be visualized in several different ways including use of quantum dots as nucleic acid labels (col. 35, lines 3-13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize quantum dots as taught by Strathmann as the nucleic acid labels generally disclosed by Labaer et al because Strathmann teaches that quantum dots provide the advantage of serving as a detection means in a hybridization assay such as the Labaer et al. hybridization assay.

24. Claims 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labaer et al [US 6,800,453], in view of Mirkin et al [US 6,361,944] and further in view of Natan et al, [6,579,726].

Labaer et al. disclose the invention substantially as claimed, as discussed above. Labaer et al fail to teach the use of spherical nanogold particles.

Mirkin et al. however teach that oligonucleotides functionalized with alkanethiols at their 5'-termini readily attach to gold nanoparticles (column 17, lines 15-20) and is well characterized (column 17, lines 8-14). Natan et al further teach that DNA can be detected utilizing metal nanoparticles that are preferably spherical (column 13, lines 31-43) and further teaches that the use of such nanoparticles leads to an 100,000 fold increase in sensitivity using detection means such as SPR (column 3, lines 40-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the 5' end of the oligonucleotides with an –SH group as taught by Mirkin et al in the invention of Labaer et al because Mirkin et al teach that such a modification provides the advantage of strongly attaching the oligonucleotides to the gold nanoparticles. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to utilize spherical gold nanoparticles, as taught by Natan et al, in the method of Lizardi et al in order to achieve a 100,000 fold increase in sensitivity using detection means such as SPR.

Conclusion

25. No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
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11/28/05